

REMARKS

By the present Amendment, claims 1-10 are cancelled and claims 11-28 are added. This leaves claims 11-28 pending in the application, with claims 11, 14 and 23 being independent.

Information Disclosure Statement

Submitted herewith is a completed form providing a listing of the U.S. patent cited in the specification to allow such patent to be made of record in this application.

Substitute Specification

The specification is revised to eliminate grammatical and idiomatic errors in the originally presented specification. The number and nature of the changes made in the specification would render it difficult to consider the case and to arrange the papers for printing or copying. Thus, the substitute specification will facilitate processing of the application. The substitute specification includes no "new matter". Pursuant to M.P.E.P. § 608.01(q), voluntarily filed, substitute specifications under these circumstances should normally be accepted. A marked-up copy of the original specification is appended hereto.

Claim Objections and Rejections Under 35 U.S.C. § 112, Second Paragraph

Original claims 1-10 stand objected to and/or rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. By the present Amendment, the originally filed claims have been rewritten to avoid the language alleged to be informal or indefinite in the Office Action. All language of the presently pending claims is now believed to be formal and definite.

The preambles of claims 14-22 uniformly use the term “device”, rather than “system”, and such use is believed to be proper. No reason is provided for the requirement to use “system” instead of “device”.

Thus, the pending claims are formal and comply with 35 U.S.C. § 112.

Rejections Under 35 U.S.C. §102 and §103

Claim 11 covers a method for endoscopic application of self-closing medical clips comprising the steps of placing a distal end of a catheter tube 1 in a body of a living being to be treated, arranging at least one self-closing clip 3 with relatively movable legs 5 in the catheter tube adjacent the distal end by an operator located on a proximal end of the catheter tube, pushing the clip out of the distal end, opening the clip by an actuator having an actuator element 17, 21 acting on the clip, being movable longitudinally in the catheter tube and actuated by the operator and having a control part converting an actuating force of the actuating element into a motion opening the legs of the clip. The actuating element is detached from the clip after opening of the clip to release the clip and close the legs of the clip to apply the clip. The clip has a first kink 13 in a first area of each leg extending outwardly and increasing a distance between the legs and a second kink 15 in a second area nearer the distal end 7 of the clip than the first area, but spaced from that distal end, extending inwardly and forming a point of mutual support for the legs.

Claim 14 is directed to a device for endoscopic application of self-closing medical clips in a body of a living being comprising a catheter tube 1, an operator, an actuator and at least one clip 3. The catheter tube has a distal end placeable in a body and a proximal end placeable outside the body. The operator is at the proximal end. The actuator extends in the catheter tube

from the operator to an area adjacent the distal end, has an actuating element 17, 21 movable longitudinally in the catheter tube and controlled by the operator, and has at least one control part with a distal end edge 25 on a sleeve-shaped receiving part 33. The clip is adjacent to and directly engages the distal end edge and has a part received in the actuating element and two adjacent legs 5. The legs have first kinks 13 extending outwardly and increasing a distance between the legs in first areas of the legs and second kinks 15 extending inwardly and forming a mutual support for the legs in second areas of the legs nearer to a distal leg end of the clip than the first area, but spaced from that distal end without the legs crossing one another. The legs are opened by the first kinks engaging the control part when the clip is inserted into the sleeve-like receiving part which converts an actuating force of the actuating element into an opening motion of the legs with the second areas engaging one another.

Claim 23 covers a self-closing medical clip comprising a crosspiece, and first and second legs extending adjacent to one another from the crosspiece to distal ends thereof and biased toward one another. The first kinks in the legs extend outwardly and increases a distance between the legs in first areas of the legs. Second kinks in the legs extend inwardly and form a mutual support for the legs in second areas of the legs. The second areas are nearer the distal ends than the first areas.

By performing the method, forming the device and forming the clip in this manner, a simple and effective mechanism is provided in which the clips can be formed and then applied. The mutual support provided by the second kinks in the second areas allow the remaining portion of the legs to pivot outwardly when the first kink is compressed with the pivoting motion being

initiated at the contact of the second kinks. None of the clips of the cited patents are formed or operated in this manner.

Claims 1-6, 8 and 9 stand rejected under 35 U.S.C. §102 as being anticipated by U.S. Publication No. 2002/0128667 to Kobayashi. The Kobayashi patent is cited for disclosing a method for endoscopic application with self-closing medical clips (Figs. 21A-21D) in which a catheter tube 1 has its distal end placed within a body. Several clips are allegedly arranged in a succession in the catheter tube and are advanced by an operator on the proximal end of the tube. The operator allegedly extrudes the compression member in the distal end, with the clips being pushed out and opened by actuating means (manipulating wire 9 and clip tightening ring 29) acting on the front most clip. The manipulating wire is allegedly moved longitudinally within the tube and actuated by the operator as the compression member moves. A control part (interpreted as the beveled end of the distal end 29, Fig. 19) allegedly converts actuating force into an opening motion of the clip legs. The actuating element after opening of the clip is allegedly detached from the clip to release it for closing of the clip leg.

Relative to the dependent claims, a pull cable is allegedly provided by manipulating wire 9 having a loop, the actuating means is allegedly provided by the beveled surface of the clip tightening ring 29 and the tube/plunger is provided by the compression member 11. The sleeve like receiving part is allegedly part provided by clip tightening ring 29. The clip allegedly has two legs with each leg having a first kink and a second kink, a distal leg end, and a rear cross piece allegedly provided by ligating wire 10. A predetermined breaking point (Fig. 7C and Fig. 2) is allegedly located between the through holes. The pull cable allegedly passes through the cross piece and has an advancing strand (wire 9) and a retreating strand (wire 9). Several clips are

allegedly within the catheter tube. The pull cable is allegedly guided through one and then through the other hole of the cross pieces of the clips. A blocking element (allegedly provided by distal end tip 2 of tube 1) is allegedly capable of permitting passage of the clip.

Claims 7 and 10 stand rejected under 35 U.S.C. §103 as being unpatentable over the Kobayashi in view of U.S. Publication No. 2002/0045909 to Kimura. The Kimura patent is cited for a collet (coil pipe 13, Fig. 7A) for attaching the distal end of a catheter tube to a clip applier which has longitudinal jaws provided by arms 13d. In support of the rejection, it is alleged that it would be obvious to modify the Kobayashi collet to include the Kimura jaws.

Relative to the Kobayashi patent, the embodiment of Figs. 21A through 21D is relied upon. In this device, the clips 14 are in an alpha shape with legs that cross one another. Specifically, the two legs are joined at a looped end and then converge toward and cross one another. After crossing, the two legs extend in a relatively longitudinal direction to an inwardly bent distal leg end alleged to correspond to the claimed second kink. From the looped end, the distance in the legs decreases until the crossing point and then increases again after the crossing point. This clip configuration does not provide the first and second kinks in the legs, as claimed, particularly since the alleged second kink is at the distal end and not spaced therefrom and does not provide the claimed mutual support.

Moreover, even if the loop at the right hand end is interpreted as a first kink and the crossover point as viewed as being a second kink, such configuration still lacks the forming a mutual support, as claimed. The Kobayashi crossover does not provide a mutual support. Moreover, claim 14 is further distinguished by reciting that the legs do not cross one another.

Accordingly, claims 11, 14 and 23 are patentably distinguishable over the Kobayashi patent. None of the other cited patents supply these deficiencies in the Kobayashi patent.

Claims 12-13 and 27, claims 15-22 and 28 and claims 24-26, being dependent upon claims 11, 14 and 23, respectively, are also allowable for the above reasons. Moreover, these dependent claims recite additional features further distinguishing them over the cited patents.

Claim 12 is further distinguishable by the form of the legs, particularly the legs not crossing one another. As noted above, the Kobayashi clip legs cross one another.

Claim 13 is further distinguishable by the additional other clips and the functional linking of the various clips.

Claim 15 is further distinguishable by the pulling element in combination with a beveled control surface on the distal end edge of the sleeve-shaped receiving part. No such beveled edge is disclosed or rendered obvious by the Kobayashi patent. Apparently the Kobayashi tightening ring 29 is cited relative to the claimed receiving part. However, that ring does not have the beveled control surface at its distal end edge.

Claim 16 is further distinguishable by the crosspiece having the two adjacent holes through which the pull cable extends. In contrast, Fig. 7C cited relative to this feature merely shows ligating wire 10 with a notch connecting manipulating wire 9 to clip 3. No crosspiece with two through holes is provided through which the manipulating cable 9 extends. The notch in Kobayashi wire 10 alleged to provide the "second hole" does not receive wire 9.

Claim 17 is further distinguishable by the breaking point between the two through holes. Neither the crosspiece of the clip 3 nor wire 10 of the Kobayashi patent has the two through holes or the breaking point between those through holes.

Claim 18 is further distinguishable by the blocking element recited therein, particularly within the overall claimed combination.

Claim 19 is further distinguishable by the blocking element being in the form of a collet with jaws. Relative to this feature, the Kimura publication is cited. However, it does not disclose the claimed features in the overall claimed combination.

Claim 20 is further distinguishable by the multiple clips within the overall claimed combination.

Claim 21 is further distinguishable by the actuator being a tube within the overall claimed combination.

Claim 22 is further distinguishable by the axial projection on the sleeve-shaped receiving part, particularly within the overall claimed combination.

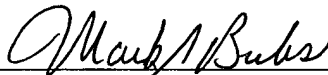
Claim 24 is further distinguishable by the legs not crossing one other.

Claim 25 is further distinguishable by the crosspiece having two holes adjacent one another with a predetermined breaking point therebetween which is not present in the Kobayashi clip, as discussed above.

Claims 26-28 are further distinguishable by the bent distal ends spaced from the second kinks.

In view of the foregoing, claims 11-28 are allowable. Prompt and favorable action is solicited.

Respectfully submitted,



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